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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,907	02/17/2004	Robert D. Black	9099-18	8994

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
RAMIREZ, JOHN FERNANDO	
ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,907	BLACK ET AL.	
	Examiner	Art Unit	
	JOHN F. RAMIREZ	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-88 and 105-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/06/07 has been entered.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments, filed 12/06/2007, with respect to the rejection of claims 43-51, 54-88, 105, 106, 108-116 and 119 under 35 USC 112, second paragraph have been fully considered. The rejection has been withdrawn as being overcome by amendment.

In response to applicant's argument that the limitations of claims 43, 105, 108-113, 118-124, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which

differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) ; In re Otto, 312 F. 2d 937, 136 USPQ 458 (CCPA 1963) Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987).

It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not-possess the characteristic relied upon. In re Spada, 911 F.2d 705, 16 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664,169 USPQ at 566 (CCPA 1971).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. MPEP 2114.

In addition, applicant alleges on page 26-29 of the remarks, that *"a processor that is programmed to provide a particular function is structurally different than other processor circuits that are programmed to provide a different function"*. However, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., *a processor programmed to compute XYZ*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43 - 55, 60 - 63, 70 - 77 and 105 - 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black (US 2002/0102212)in view of Loeb et al. (US 7,096,053).

Black discloses methods of providing labeled antibodies in vivo to tissue having antigens that specifically bind a fluorescently labeled antibody. A first optical radiation is emitted into tissue to excite the labeled antibody bound to the antigen in vivo. A second optical radiation that is emitted by the excited labeled antibody in response to the excitation thereof can be detected in vivo (paragraph 0010). A platform comprising an optical radiation source which emits a first optical radiation that excites fluorescent labels. Once excited, the fluorescent labels emit a second optical radiation which may be selected to penetrate bio-fouling tissue. The optical radiation source can be a high power LED. An optical radiation detector can detect the second optical radiation through bio-fouling tissue and can be a photodiode or phototransistor. The detector can include an optical absorption filter to reduce the effects of background noise. The detector is located about 500 micrometers from the bound complexes (paragraph 0037 - 0040). The optical radiation source, detector and matrix can operate in conjunction with a processor circuit which can provide input to a telemetry system (paragraph 0053 - 0055). The in vivo system can be implanted for in vivo use whereby the ex vivo system can control operations of the system. The in vivo system can include an indicator that provides power from the ex vivo system via an inductively powered signal from the ex vivo system. The system has a diameter of approximately 2 mm and may be cylindrical (paragraph 0056 - 0059). The package size and geometry allow for a range of coatings such as diamond like carbon or glass. Continuous monitoring of the implanted sensor is possible so that reaction kinetics can be monitored (paragraph 0062).

Black does not specifically teach that excitation light is at least 400 nm.

Loeb discloses a biosensing device for detecting biological analytes which include a biosensing element that can remain implanted for extended periods of time (abstract). Changes in fluorescence intensity and/or wavelength caused by binding of an analyte with a biosensing material, an optical fiber can transmit fluorescing evidence of the analyte from within a patient's body to an external analyzer. The system can be useful for monitoring levels of bioactive compounds that have narrow margins between safe and toxic levels (e.g. anticancer, immunosuppressive or anticoagulant drugs) or whose pharmacokinetics are uncertain. The sensing materials are based on antibodies, enzymes, etc. whose specific binding or rate of reaction depends on the concentration of analyte in adjacent fluids (column 3, lines 20+). The device comprises a light source such as a laser diode capable of producing, for example 20 mW - 24 mW. The excitation wavelength produced by the light source may be in the range of 470 - 490 nm, which is known to effectively excite certain fluorophores (column 6, lines 27+). Repeated measurements of analyte may be performed for a selected time such as at least one to three months (column 13, lines 28 - 29).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize an excitation light for causing excitation of flu0r-labeled antibodies having a wavelength of at least 400 nm in the device of Black, for exam. pie, because Black teaches that the purpose of the excitation light is to excite fluor-labled antibodies, and one would have been motivated to do so because Loeb teaches the importance utilizing a wavelength which is known to excite certain fluorophores (i.e. 470 - 490 nm) for in vivo fluorescence measurements via an implantable device. Regarding

the limitations of claims 43 and 105, wherein the detection system is "for detecting fluorescence in a body of a subject associated with an administered fluorescent analyte, the fluorescent analyte including..." and wherein "the fluorescent analyte is administered from a source other than the at least one sensor, "and wherein the processor is "configured to monitor intensity over time associated with one or more of the uptake and retention of the fluorescent analyte...", it is noted that the instant claims are product claims, and the recitation of the intended use of the product has not been given patentable weight to distinguish over the cited prior art references because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The product (detection system) claims are examined on the basis of their structural elements (i.e. a sensor, a processor, etc.), not on what type of analyte is to be detected via the detection system. Furthermore, method steps such as "administration" are not given patentable weight in product claims.

Regarding the limitations of **claims 43, 108, 112, 113, 117, 119, 121,122, 123, 124** wherein the detection system is "for detecting fluorescence in a patient's body associated with an administered fluorescently labeled chemotherapeutic agent" or "for monitoring pharmacokinetics and/or pharmacodynamics" or "for determining a phenotypic response of a patient to a selected drug therapy", or the processor is "configured to monitor intensity over time associated with one or more of the uptake and retention of the fluorescent analyte..." or "configured to analyze the detected intensity

over time and predict whether the subject will have a favorable response to cancer therapy," or "configured to calculate a dose of chemotherapeutic agent received at local tissue based on the intensity data over time..." or "configured to predict a bioresponse to a chemotherapeutic agent" or "configured to direct output of the excitation signal to local tissue. :." and "configured to monitor fluorescence intensity of the fluorescently labeled analyte.., to determine the pharmacokinetics and/or pharmacodynamics at the target site" or "configured to monitor a patient that has undergone gene therapy," or "configured to detect fluorescence to confirm micelle concentration" or "configured to monitor fluorescence intensity.., and predict a phenotypic response of the patient to the therapeutic agent at the target site" it is noted that the instant claims are product claims, and the recitation of the intended use of the product has not been given patentable weight to distinguish over the cited prior art references because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The product (detection system) claims are examined on the basis of their structural elements (i.e. a sensor and a processor). Because the cited art teaches a processor in conjunction with a sensor, any processor would be capable of being "configured" to perform the claimed intended use functions.

Regarding the limitations of **claims 43, 105, 109 - 111, 117, 118 or 120,** wherein the fluorescent analyte is a fluor-labeled analyte, or a fluor-labeled antibody, or a fluor-

labeled chemotherapeutic agent, or is "configured to increase or decrease in response to a level or protein" it is noted that the instant claims are product claims, and the recitation of the intended use of the product has not been given patentable weight to distinguish over the cited prior art references because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The product (detection system) claims are examined on the basis of their structural elements (i.e. a sensor, a processor, etc.), not on what type of analyte is to be detected via the detection system, because what is being detected by a device does not impose structural limitations on the device itself.

Regarding the limitation of **claim 48,** wherein at least one sensor is a plurality of sensors, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Regarding the limitation the excitation light is configured to generate an excitation light that is able to penetrate light that is at least 2 mm to about 20 mm away, it is interpreted, in the absence of the contrary the excitation light of Loeb would inherently have the same properties because the same wavelength of light is used and is operated at the same power (i.e. 20 mW).

Claims 43 - 88 and 105 - 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black (US 2002/0102212) in view of Loeb et al. (US 7,096,053), in further view of Colvin et al. (US 6,330,464) and Lesho (US 2004/0054385).

Black, in view of Loeb, as set forth above, fail to disclose that the excitation light is pulsed. However, the use of pulsed excitation light in implantable fluorescence sensors is well-known in the art as shown by e.g., Colvin and Lesho. Colvin teaches an optical-based sensor for detecting the presence of amount of an analyte (abstract). Radiation emitted from a source strikes and causes an indicator to fluoresce (column 1, lines 26 - 40). The source of radiation, such as an LED may be powered by external means (column 2, lines 40 - 55). The capsule may include glass or epoxy resin. A plurality or radiation sensors may be used (column 24) and the LEDs can be activated for a fraction of a second, which one LED remaining off while the other is on (i.e. pulsed) and separate readings can be made due to temporal differences in emission (column 25, lines 10 - 20). The devices of Colvin also include photodiode, etc. detectors which can be present on the top, sides, etc. of the device (column 35 - 36).

Lesho teaches an implantable fluorescence sensor for detecting the concentration or presence of an analyte in the human body (paragraph 0002). The device optoelectorons circuitry, an RF oscillator, etc. for retrieving information from the sensor device and a processor for receiving and processing information signals (paragraphs 0007- 0019). The device comprises a radiation source (e.g. LED) and a

photodiode detector, and light intensity may be pulsed with a 50% duty cycle (paragraph 0074).

It would have been obvious to one of ordinary skill .in the art at the time of the instant invention to provide pulsed excitation light in the devices of Black, as modified by Loeb above, because it is well known in the art that pulsed excitation light is used in similar implantable fluorescence sensors. One would have been motivated to do so because Colvin and Lesho teach that such modifications allow for e.g. separate readings for temporal differences in emission, etc. Regarding claimed limitations regarding the size of the detector in comparison with the width of the sensor body, etc. it is interpreted that such factors such as the size and positioning of detector within the sensor body and the pulse cycle of the excitation light are elements of design of the sensor which may be variable without departing from the scope of the combined teachings of Black, Loeb, Colvin and/or Lesho because each of the cited references teach the presence of a photodiode detector and excitation light, and thus it would have been well within the skill level of the ordinary artisan to provide slight variations in such variables.

Allowable Subject Matter

Claim 117 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

/J. F. R./
Examiner, Art Unit 3737